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09/578,391	05/25/2000	Akiro Sato	0694-132	6158

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EXAMINER

ROBERTS, PAUL A

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 04/09/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/578,391

Applicant(s)

Sato

Examiner

Paul A Roberts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 15 is/are rejected.
- 7) ☒ Claim(s) 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

During a telephone conversation with Jae Kim on 8/02/02 a provisional election was made with traverse to prosecute the invention of group I, claims 1-11, 15,16. Affirmation of this election must be made by applicant in replying to this Office action.

No affirmation was made by the applicant to the election that took place by Jae Kim in the response filed 3-6-03. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claim 1 is still rejected under 35 U.S.C. 102(b) as being anticipated by Tessmann et al., 5167614. Tessmann et al. teaches a cylindrical device with a plurality of protrusions/protuberances emanating from the plate members. This device can be used for performing an anastomosis without alteration to the device. Further, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as

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compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 3, 4, 6, 9, 10, & 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schnepf-Pesch et al. 5354309, in view of Tessmann et al.

2. Regarding claim 1, Schnepf-Pesch et al. discloses a device with a cylindrical body that contains at least one plate member. He fails to show that this device can be equipped with the protrusions/protuberances that Tessmann et al. teaches in 5167614, see figure 2. It would have been obvious to one skilled in the art at the time of the invention to place the protrusions detailed by Tessmann et al. onto the Schnepf-Pesch et al. device to help reduce the probability of the device from slipping.

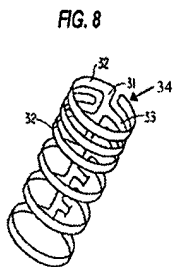
3. Regarding claim 2, Schnepf-Pesch et al. teaches the use of a cylindrical device that would be inserted into a lumen during surgery (see figure 6.) He fails to teach that this device can be equipped with the protrusions that Tessmann et al. teaches in 5167614, see figure 2. It would have been obvious to one skilled in the art at the time of the invention to place the

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protrusions detailed by Tessmann et al. onto the Schnepf-Pesch et al. device to help reduce the probability of the device from slipping.

4. Regarding claim 3, the modified Schnepf-Pesch et al. device (in figure 6) has elastic properties where the diameter can be compressed and expanded. The stent's size can be lengthened or shortened by pulling or pushing on the end of the spring. It can also be thickened or thinned by twisting the spring.

5. Regarding claim 4, Schnepf-Pesch et al. teaches the use of an anastomosis member that has a stress strain characteristic (all springs do.) Further, it has a region with a low-rigidity part that is deformable along the curvature. This part can be found at any location along the spring, since the entire spring is deformable. Additionally, in figure 8, the element labeled 34 can be deformed to ensure that the device fits tightly inside the first and second blood vessel.

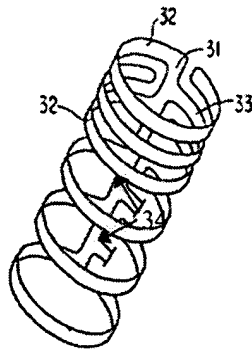


6. Regarding claim 6, the modified Schnepf-Pesch et al. device has a plate member wound into a helical spiral (see figure 6.)

7. Regarding claim 9, Schnepf-Pesch et al. teaches a device with a plurality of plate members arranged in parallel with one another and containing a plurality of connecting members connecting said plate members with one another. (see figure 8.)

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8. Regarding claim 10, the connecting members are made of an elastic, wire material. Item 34, in the below figure, points to two different wire members. Schnepf-Pesch et al. states that the shape can be a flat, metal sheet as illustrated, or the shape can be more similar to a round conventional wire in column 2, line 33. Finally, applicant should note that all metals display some elastic properties under minimal stress.

FIG. 8

9. Regarding claim 11, the modified Schnepf-Pesch et al. device has a plate made of a NiTi memory alloy (column 2, line 11.)

10. Regarding claim 15, the Schnepf-Pesch et al. discloses a device that is used in the manner claimed by the applicant in claim 15. The device could be used to help prevent a blood tubule from collapsing after an anastomosis via suturing the two vessels together. It would have been obvious to one skilled in the art at the time of the invention to delineate the method outlined in applicant's claim # 15, for the purpose of preventing a vessel from collapsing during and after an anastomosis.

11. Claims 1, 5, 7, & 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff et al., in view of Tessmann et al.

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12. Regarding claim 1 and 5, Wolff et al. discloses a device that can be used as an anastomical tool to secure to lumens together. The device is cylindrical and contains a plurality of ziz-zag patterns on its plate members figure 4. Wolff et al. fails to teach the practice of adding protrusions/protuberances to the device to decrease slippage. Tessmann et al. teaches that a stent may be equipped with protrusions/protuberances to reduce the possibility of slippage in the lumen. It would have been obvious to one skilled in the art at the time of the invention to equip the Wolff et al. device with protrusions designed by Tessmann et al. in order to reduce the probability of luminal slippage. Further, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

13. Regarding claim 7 & 8 Wolff et al. teaches a device with a rhombic portion. Since a rhombic pattern is also a lattical pattern, he also teaches a device with a lattice portion (see figure 4.)

Allowable Subject Matter

14. Claim 16 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. The following is a statement of reasons for the indication of allowable subject matter: Regarding claim 16, Sakura illustrates the method one can use to apply an anastomical device in figures 4-9 and also describes the method in claim 27 of the Sakura patent. The steps comprise the following:

- inserting the device into the lumens of one vessel

- inserting the lumen into the device with other vessel

Through the diagram, one skilled in the art can see that the skin is folded over the protrusion as shown in figure 8, item 12. However, Sakura's device does not disclose a plate member, and further, the applicant's invention discloses a method where one places both sides the anastomosis device into the lumen, and inverts one of the lumens. Sakura's invention does not disclose either limitation.

Response to Amendment

14. The Tessmann device 5167614 contains protrusions as stated. It is well known in the art that a protrusion is also encompasses a protuberance. For reference please see Williams 5,593,434 which demonstrates an expanding stent with raised elements (15.) Williams refers to these elements as both protuberances and protrusions throughout the specification. Lines 45-43, col. 1 states both terms referring to the same raised element on the stent. Thus Tessmann anticipates the use of protuberances or protrusions. A protrusion is simply a raised surface and does not mean a sharp raised surface as indicated by the applicant.

15. Regarding the argument that adding protrusions to the Schnepf-Pesch et al. ("Schnepf") would be inadvisable for an anastomosis, the applicant's argument is spurious for the following reasons. The Tessmann device expands. Please see figure 8. The protrusions/protuberances are small enough that they grip the vessel but do not destroy the vessel. The raised surfaces decrease slippage. Additionally, the Tessmann raised surfaces would only engage the surface of the vessel when the device is rotated as denoted in the Tessmann reference. When the Schnepf device is expanded, the vessel walls will marginally slide, but will not snag the Tessmann raised surfaces, until the device has completed its expansion. At this point, the combined Tessmann-

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Schnepp device would be twisted and the raised surfaces engaged into the vessel wall. The combination device would not damage the tissue and the motivation to combine the references is proper because the combined device would more securely hold an anastomosis than the Schnepp device alone.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Patent Number	Reason for Includance
5593434	A stent with protrusions/protuberances
5782903	Stent and method
6053943	Anastomosis method and apparatus
6517573	Anastomosis method and apparatus
4950227	Stent with protuberances
4955859	Stent with protuberances


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A Roberts whose telephone number is (703) 305-7558. The examiner can normally be reached on 7:30-3:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Paul Roberts
April 7, 2003


MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700